



Docket: 02-321

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Robert E. Richard et al.  
Application No.: 10/632,061  
Date Filed: 07/31/2003  
Title: IMPLANTABLE OR INSERTABLE MEDICAL DEVICES CONTAINING  
ACRYLIC COPOLYMER FOR CONTROLLED DELIVERY OF  
THERAPEUTIC AGENT  
Group Art Unit: 1615  
Atty. Docket No.: 02-321

INFORMATION DISCLOSURE STATEMENT (IDS)

Mail Stop DD  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

SIR:

In accordance with 37 C.F.R. §1.56 and in compliance with 37 C.F.R. §§1.97 and 1.98, the references listed on attached Form PTO/SB/08 and/or subsequently identified herein, are being submitted herewith for consideration by the United States Patent and Trademark Office.

I. COPIES

- a. ☒ A legible copy of (i) each U.S. and foreign patents; (ii) each publication or that portion which caused it to be listed; and (iii) all other information or that portion which caused it to be listed, is included herewith.
- b. ☐ Any patents, publications or other information which are listed on PTO/SB/08 which are not enclosed herewith were previously cited by or submitted to the PTO in one of the following applications which has been relied upon for an earlier filing date under 35 U.S.C. §120:

U.S. Serial Number

U.S. Filing Date

II. CONCISE EXPLANATION OF THE RELEVANCE (check at least one box)

- a. ☒ Except as may be indicated below in (b) of this section, all of the patents, publications or other information are in the English language (concise explanation not required).
- b. ☐ A concise explanation of the relevance of all patents, publications or other information listed that is not in the English language is as follows:
- c. ☐ The following additional information is provided for the Examiner's consideration:

III. ☐ CROSS REFERENCE TO RELATED APPLICATION(S)

The Examiner is advised that the following co-pending application(s) contain(s) subject matter that may be related to the present application. By bringing this (these) applications to the Examiner's attention, Applicant(s) does(do) not waive the confidentiality provisions of 35 U.S.C. §122.

Serial No.

Filing Date

Art Unit

FEES

- IV. ☒ THIS IDS IS BEING FILED UNDER 37 C.F.R. §1.97(b): (check one box)
- a. ☐ within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d) (37 C.F.R. §1.97(b)(1)). No fee or statement is required.
  - b. ☐ within three months of the date of entry of the national stage as set forth in § 1.491 in an international application (37 C.F.R. §1.97(b)(2)). No fee or statement is required.
  - c. ☒ before the mailing date of a first Office Action on the merits (37 C.F.R. §1.97(b)(3)). No fee or statement is required.
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- V. ☐ THIS IDS IS BEING FILED UNDER 37 C.F.R. §1.97(c): (check one box)
- before the mailing date of any of a Final Office Action under 37 C.F.R. §1.113, a Notice of Allowance under 37 C.F.R. §1.311, or an action that otherwise closes prosecution in the application (See 37 C.F.R. §1.97(c)).
- a. ☐ No statement; therefore, charge deposit account 50-1047 the fee set forth in 37 C.F.R. §1.17(p).
  - b. ☐ See the statement below. No fee is required.
- VI. ☐ THIS IDS IS BEING FILED UNDER 37 C.F.R. §1.97(d):
- on or before payment of the issue fee and is accompanied by the following:
- 1) a statement under 37 C.F.R. §1.97(e) as provided below; and
  - 2) charge deposit account 50-1047 the petition fee set forth in §1.17(p).
- VII. ☐ STATEMENT UNDER 37 C.F.R. §1.97(e) (check only one box, if applicable)
- The undersigned hereby states that
- a. ☐ each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of IDS; or
  - b. ☐ no item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application, and to knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in the IDS was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of this statement, or
  - c. ☐ some of the items of information contained in the IDS were cited in a communication from a foreign Patent Office. As to this information, the undersigned states that each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby states that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application or, to the knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in the IDS was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of this statement.
- VIII. PAYMENT OF FEES
- ☐ A check in the amount of \_\_\_\_\_ is enclosed for the above-identified fee(s).
  - ☐ Please charge Deposit Account No. 50-1047 in the amount of \$180.00 for the above-indicated fee(s).
  - ☒ If Applicant has overlooked any additional fees, or if any overpayment has been made, the Commissioner is hereby authorized to credit or debit Deposit Account 50-1047.
  - ☐ Two Copies of this paper are attached for Deposit Account charges and debits.

It is Applicant(s)' opinion that the claims presently on file patently distinguish the present invention from each of these references. The above references are being cited only in the interests of candor and without any admission that they constitute statutory prior art or contain matter which anticipates the invention or which would render the same obvious, either singly or in a combination, to a person of ordinary skill in the art.

If the Examiner has any questions concerning this IDS, he/she is requested to c ntact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule (with a petition if necessary) and charge the appropriate fee to Deposit Account No. 50-1047.

Respectfully submitted,



David B. Bonham  
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Enclosures: ☒ PTO/SB/08  
☒ References  
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SUPPLEMENTAL  
INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

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Sheet

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of

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## Complete if Known

Application Number	10/632,061
Filing Date	07/31/2003
First Named Inventor	Robert E. Richard et al.
Group Art Unit	1615
Examiner Name	Unassigned
Attorney Docket Number	02-321

Examiner Initials*	Cite No. 1	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM- DD-YYYY
		Number	Class/Subclass		
	1.	5,741,331	623/11	Pinchuk	04/21/1998
	2.	4,946,899	525/244	Kennedy et al.	08/07/1990
	3.	2002/0107330	525/242	Pinchuk et al.	08/08/2002
	4.	5,879,697	424/422	Ding et al.	03/09/1999
	5.	6,099,562	623/1.46	Ding et al.	08/08/2000
	6.	5,304,121	604/53	Sahatjian	04/19/1994
	7.	5,716,981	514/449	Hunter et al.	02/10/1998
	8.	5,616,608	514/449	Kinsella et al.	04/01/1997
	9.	5,733,925	514/449	Kunz et al.	03/31/1998
	10.	5,258,020	623/1	Froix	11/02/1993
	11.	6,335,029 B1	424/423	Kamath et al.	01/01/2002
	12.	6,280,411 B1	604/103.05	Lennox	08/28/2001
	13.	5,954,706	604/509	Sahatjian	09/21/1999
	14.	2002/0045706 A1	525/100	Houston et al.	04/18/2002
	15.	5,856,367	521/64	Barrows et al.	01/05/1999

Examiner Initials*	Cite No. 1	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM- DD-YYYY	T
		Office <sup>3</sup>	Number <sup>4</sup>	Class/Subclass			

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<sup>1</sup> Unique citation designation number. <sup>2</sup> See Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English Language Translation is attached.



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STATEMENT BY APPLICANT

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Sheet 2 of 3

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Attorney Docket Number	02-321

## OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	1.	James F. Beecher et al., "Morphology and Mechanical Behavior of Block Polymers," <i>J. Polymer Sci. Part C</i> , no. 26 (1969), pp. 117-134.	
	2.	<i>Diblock and Triblock Copolymers</i> , pp. 141-151.	
	3.	Kohtaro Kimishima et al., "Control of Self-Assembled Structures in Binary Mixtures of A-B Diblock Copolymer and A-C Diblock Copolymer by Changing the Interaction between B and C Block Chains," <i>Macromolecules</i> , 1999, no. 32, pp. 2585-2596.	
	4.	Richard J. Spontak et al., "Phase Behavior of Ordered Diblock Copolymer Blends: Effect of Compositional Heterogeneity," <i>Macromolecules</i> , 1996, no. 29, pp. 4494-4507.	
	5.	Hong G. Jeon et al., "Microphase and Macrophase Transitions in Binary Blends of Diblock Copolymers," <i>Macromolecules</i> , 1999, no. 32, pp. 1803-1808.	
	6.	Immiscible Polymer Blends. <a href="http://www.psrc.usm.edu/macrog/iblend.htm">http://www.psrc.usm.edu/macrog/iblend.htm</a> .	
	7.	L. H. Sperling, <i>Polymeric Multicomponent Materials: An Introduction</i> , New York (John Wiley & Sons), pp. 284-285.	
	8.	Joseph C. Salamone, ed., <i>Concise Polymeric Materials Encyclopedia</i> , Boca Raton (CRC Press, 1999), pp. 812-814.	
	9.	Reference: Polymer Properties. <a href="http://www.sigmaaldrich.com/img/assets/3900/Thermal_Transitions_of_Homopolymers.pdf">http://www.sigmaaldrich.com/img/assets/3900/Thermal_Transitions_of_Homopolymers.pdf</a> .	

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Sheet 3 of 3

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	10.	The Glass Transition. <a href="http://www.psrm.usm.edu/macrog/tg.htm">http://www.psrm.usm.edu/macrog/tg.htm</a> .	
	11.	C. Moineau et al., "Synthesis and Characterization of Poly(methyl methacrylate)- <i>block</i> -poly( <i>n</i> -butyl acrylate)- <i>block</i> -poly(methyl methacrylate) Copolymers by Two-Step Controlled Radical Polymerization (ATRP) Catalyzed by NiBr <sub>2</sub> (PPh <sub>3</sub> ) <sub>2</sub> , 1," <i>Macromolecules</i> , 1999, no. 32, pp. 8277-8282.	
	12.	Devon A. Shipp et al., "Water-Borne Block Copolymer Synthesis and a Simple and Effective One-Pot Synthesis of Acrylate-Methacrylate Block Copolymers by Atom Transfer Radical Polymerization," <i>Am. Chem. Soc., Polym. Prep.</i> , 1999, vol. 40, pp. 448-449.	
	13.	Y.K. Chong, "A More Versatile Route to Block Copolymers and Other Polymers of Complex Architecture by Living Radical Polymerization: The RAFT Process," <i>Macromolecules</i> , vol. 32, 1999, pp. 2071-2074.	
	14.	Kathryn L. Beers et al., "Controlled/Living Radical Polymerization in the Undergraduate Laboratories. 1. Using ATRP to Prepare Block and Statistical Copolymers of <i>n</i> -Butyl Acrylate and Styrene," vol. 78, no. 4, Apr. 2001, pp. 544-547.	
	15.	Michael J. Monteiro et al., "Synthesis of Butyl Acrylate-Styrene Block Copolymers in Emulsion by Reversible Addition-Fragmentation Chain Transfer: Effect of Surfactant Migration upon Film Formation," <i>Journal of Polymer Science: Part A: Polymer Chemistry</i> , vol. 38, 2000, pp. 4206-4217.	
	16.	Kelly A. Davis et al., "Preparation of Block Copolymers of Polystyrene and Poly( <i>t</i> -butyl acrylate) of Various Molecular Weights and Architectures by Atom Transfer Radical Polymerization," <i>Journal of Polymer Science: Part A: Polymer Chemistry</i> , vol. 38, 2000, pp. 2274-2283.	
	17.	Karine Tortosa et al., "Synthesis of Polystyrene- <i>block</i> -poly(butyl acrylate) Copolymers Using Nitroxide-Mediated Living Radical Polymerization in Miniemulsion," <i>Macromolecular Rapid Communications</i> , vol. 22, no. 12, 2001, pp. 957-961.	
	18.	Ben Reeves, "Recent Advances in Living Free Radical Polymerization," University of Florida, Nov. 20, 2001, pp. 1-14.	

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